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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/841,158 | 04/25/2001 | Ellen M. Beasley | CL001229 | 4168 |

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| EXAMINER | |
|---|---|
| HAMUD, FOZIA M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/841,158 | Beasley et al. |
| **Examiner** | **Art Unit** |
| Fozia Hamud | 1647 |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) [X] Responsive to communication(s) filed on *Aug 26, 2002*.

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) [X] Claim(s) *4, 8, 9, and 24-29* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *4, 8, 9, and 24-29* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) [X] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) [ ] Interview Summary (PTO-413) Paper No(s). _____
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other: _____

## DETAILED ACTION

***Election/Restriction***

1a. Applicant's election of Group III (claims 4-5, 8-11, 22-23) and the nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:1 and 5, in Paper No.7, filed on 26 August 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

1b. Claims 4 and 8 have been amended, claims 1-3, 5-7, 10-23 have been canceled and new claims 24-29 have been added in the amendment filed in Paper No.7, filed on 26 August 2002. Thus claims 4, 8-9 and 24-29 are pending and under consideration by the examiner.

The restriction requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 U.S.C. § 101***

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2a. Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 9 recites " host cell containing...", which encompasses the host cell, as it occur in nature, for example, as a gene therapy patient. However, since Applicants do not intend to claim a naturally occurring products amendment of the claim to show the hand of man would obviate this rejection. It is suggested that claim 9 to recite " an isolated host cell..... .....". Appropriate correction is required.

***Claim Rejections - 35 U.S.C. § 101/112***

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3a. Claims 4, 8-9 and 24-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 4, 8-9 and 24-29 of the instant invention are directed to an isolated nucleic acid molecule which consists of the nucleotide sequence set forth in SEQ ID NO:1 or 5, said nucleic acid encoding the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:3, a vector comprising said nucleic acid , a host containing said vector and a method of producing the encoded protein.

The specification describes the polypeptide of SEQ ID NO:3, encoded by the claimed nucleic acid as being a member of the transcobalamin II secreted protein subfamily, (page 5, third paragraph). Instant specification discloses the nucleotide sequence of a cDNA molecule that encodes a secreted protein, and the predicted amino acid sequence for the encoded protein, (see figures 1 and 2). The specification also discloses that one isoform of the secreted protein encoded by the claimed nucleic acid is expressed in adult adrenal gland, mammary gland, retinoblastoma, adenocarcinoma cell line, embryonal carcinoma cell line, adult uterus, adult head-neck, and leukocytes. However, the specification does not disclose any information regarding physiologic activity or functional characteristics of the protein encoded by the claimed nucleic acid. Instant specification states that providing the start and stop codons of the claimed nucleic acid and the tissue expression profile of

the claimed nucleic acid and the protein it encodes, enables one of ordinary skill in the art to readily determine specific uses for the claimed nucleic acid and the protein it encodes. (see page 6, description for figures 1 and 2). However, all nucleic acids that encode proteins have start and stop codons, therefore, this does not afford the claimed nucleic acid specific utility. With respect to tissue distribution, it appears that the claimed nucleic acid and the protein it encodes are expressed in disparate tissues and organs, and in some normal tissue, as well as in some cancerous tissues and cell lines, therefore, it is unclear what is the significance of this expression. One asserted utility for the protein encoded by the claimed nucleic acid is to use it a s a model for the development of human therapeutic targets and aid in the identification of therapeutic proteins, however, instant specification establishes no connection between the expression of the claimed nucleic acid or the polypeptide it encodes and any disorder. Thus one of ordinary skill in the art would not know which disorders to target using the claimed nucleic acid or the encoded protein. Instant specification discloses that the protein encoded by the claimed nucleic acid is a member of the transcobalamin II secreted protein family, (see page 5). The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Skolnick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Skolnick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, since the specification does not provide an activity for the protein encoded by the claimed nucleic acid, one of ordinary skill in the art would not be able to predict what activity would be possessed by the protein of the instant application, based solely is a member of the transcobalamin II secreted protein family. Thus, the claimed

invention is directed to a polynucleotide encoding a polypeptide of as yet undetermined function or biological significance. Therfore, unless Applicants demonstrate that the claimed nucleic acid encodes a secreted transcobalamin II polypeptide, the physiological significance or the biological role of the instant polynucleotide and the protein it encodes is yet unknown, therefore, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

4b. Claims 4, 8-9 and 24-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. No biological activity was assayed or determined for the protein encoded by the claimed nucleic acid. Therefore, there is no specific and substantial asserted utility or well established for the nucleic acid of the instant Application or the encoded protein. Although the specification provides the nucleotide sequence of the claimed nucleic acid and the deduced amino acid sequence of the protein it encodes, one of ordinary skill in the art would not know how to use said nucleic acid or the encoded protein, because Applicants have not provided any information regarding functional activity, physiological characteristics or biological significance of said protein or the nucleic acid encoding it.

***Conclusion***

5. No claim is allowed.

***Advisory Information***

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
09 September 2002

Gary L. Kunz